ASCENSION ORTHOPEDICS, INC
8700 CAMERON ROAD, SUITE 100
AUSTIN, TEXAS 78754

Summary of Safety and Effectiveness

K111799
p1/2

AUG 19 2011

Sponsor:

Ascension Orthopedics, Inc.
8700 Cameron Road, Suite 100
Austin, TX 78754-3832

Contact Person:

Bradley W. Strasser
Regulatory Affairs Specialist
512-836-5001 ext. 1541

Date:

24 June 2011

Trade Name:

NuGait™ Subtalar Implant System

Common Name:

Subtalar Arthroereisis Implant

Product Code:

HWC – Screw, Fixation, Bone

Classification:

21 CFR §888.3040 – Smooth or threaded metallic bone fixation fastener.

Panel:

Orthopedic

Predicate Device:

Sub-Talar Lok™ Arthroereisis Implant System; K080280, cleared 14 March 2008; manufactured by Instratek, Inc.

Device Description:

The *NuGait* Subtalar Implant System consists of a one-piece arthroereisis implant designed to stabilize the subtalar joint of the hyperpronated foot and associated instrumentation. The *NuGait* implant is constructed of Ti-6Al-4V ELI titanium alloy and is offered in 5 sizes to fit a range of anatomies. The subject device is also cannulated to allow precise insertion when used with a guide wire and system instrumentation. The outer surface of the implant features a helical thread to aid fixation within the sinus tarsi. Each *NuGait* is packaged individually and sterilized via gamma radiation. These devices are intended for single use only.

K111799
p 2/2

Intended Use:	The *NuGait* Subtalar Implant System restricts excessive subtalar pronation in the downward, forward, and medial planes, providing for a more normal subtalar joint motion in patients. The *NuGait* Subtalar Implant System is intended for the following pathological conditions resulting from disease, injury, or other trauma: • Hypermobile pes valgus; • Posterior tibial tendon dysfunction; • Severe pronation; • Subtalar instability; • Hypermobile flexible congenital flat foot.
Basis of Substantial Equivalence:	The *NuGait* Subtalar Implant System has the same technological characteristics and intended use as the predicate device. The subject device is also manufactured from equivalent materials. These points and engineering analysis form the basis for substantial equivalence, and the differences between the subject device and predicate do not raise new issues of safety or effectiveness.
Non-Clinical Performance Data:	In order to support substantial equivalence, the following non-clinical performance data was gathered: • Bending Strength Evaluation
Clinical Performance Data:	Clinical performance data were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ascension Orthopedics, Inc.
% Mr. Bradley W. Strasser
8700 Cameron Road, Suite 100
Austin, TX 78754-3832

AUG 19 2011

Re: K111799
Trade/Device Name: *NuGait*™ Subtalar Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: June 24th, 2011
Received: June 27th, 2011

Dear Mr. Strasser,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 111799

Device Name:

NuGait™ Subtalar Implant System

Indications for Use:

The *NuGait™* Subtalar Implant System restricts excessive subtalar pronation in the downward, forward, and medial planes, providing for a more normal subtalar joint motion in patients. The *NuGait* Subtalar Implant System is intended for the following pathological conditions resulting from disease, injury, or other trauma:

- Hypermobile pes valgus;
- Posterior tibial tendon dysfunction;
- Severe pronation;
- Subtalar instability;
- Hypermobile flexible congenital flat foot.

The *NuGait* Subtalar Implant System implants are intended for single use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111799